



UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

SEP 23 1998

#21

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,298,520 was filed on August 7, 1998, under 35 U.S.C. § 156. The declaration referenced in the cover letter was not received by the undersigned. Applicant was requested to fax a copy of the declaration to the Office and the faxed copy is included herewith.

The assistance of your Office is requested in confirming that the products identified in the application, MAXALT® (rizatriptan benzoate) and MAXALT-MLT™, have been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before their first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the products were approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Philippe L. Durette
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